

PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

(Chapter II of the Patent Cooperation Treaty)

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference SCB 860 PCT	FOR FURTHER ACTION See Form PCT/IPEA/416																	
International application No. PCT/EP2004/007374	International filing date (day/month/year) 06.07.2004	Priority date (day/month/year) 11.07.2003																
International Patent Classification (IPC) or national classification and IPC A61K35/78, A61P15/00																		
Applicant INDENA S.P.A.																		
<ol style="list-style-type: none"> This report is the international preliminary examination report, established by this International Preliminary Examining Authority under Article 35 and transmitted to the applicant according to Article 36. This REPORT consists of a total of 5 sheets, including this cover sheet. This report is also accompanied by ANNEXES, comprising: <ol style="list-style-type: none"> <input type="checkbox"/> <i>(sent to the applicant and to the International Bureau) a total of sheets, as follows:</i> <ul style="list-style-type: none"> <input type="checkbox"/> sheets of the description, claims and/or drawings which have been amended and are the basis of this report and/or sheets containing rectifications authorized by this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions). <input type="checkbox"/> sheets which supersede earlier sheets, but which this Authority considers contain an amendment that goes beyond the disclosure in the international application as filed, as indicated in item 4 of Box No. I and the Supplemental Box. <input type="checkbox"/> <i>(sent to the International Bureau only) a total of (indicate type and number of electronic carrier(s)) , containing a sequence listing and/or tables related thereto, in computer readable form only, as indicated in the Supplemental Box Relating to Sequence Listing (see Section 802 of the Administrative Instructions).</i> 																		
<ol style="list-style-type: none"> This report contains indications relating to the following items: <table border="0"> <tr> <td><input checked="" type="checkbox"/> Box No. I</td> <td>Basis of the opinion</td> </tr> <tr> <td><input type="checkbox"/> Box No. II</td> <td>Priority</td> </tr> <tr> <td><input type="checkbox"/> Box No. III</td> <td>Non-establishment of opinion with regard to novelty, inventive step and industrial applicability</td> </tr> <tr> <td><input type="checkbox"/> Box No. IV</td> <td>Lack of unity of invention</td> </tr> <tr> <td><input checked="" type="checkbox"/> Box No. V</td> <td>Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement</td> </tr> <tr> <td><input type="checkbox"/> Box No. VI</td> <td>Certain documents cited</td> </tr> <tr> <td><input type="checkbox"/> Box No. VII</td> <td>Certain defects in the international application</td> </tr> <tr> <td><input type="checkbox"/> Box No. VIII</td> <td>Certain observations on the international application</td> </tr> </table> 			<input checked="" type="checkbox"/> Box No. I	Basis of the opinion	<input type="checkbox"/> Box No. II	Priority	<input type="checkbox"/> Box No. III	Non-establishment of opinion with regard to novelty, inventive step and industrial applicability	<input type="checkbox"/> Box No. IV	Lack of unity of invention	<input checked="" type="checkbox"/> Box No. V	Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement	<input type="checkbox"/> Box No. VI	Certain documents cited	<input type="checkbox"/> Box No. VII	Certain defects in the international application	<input type="checkbox"/> Box No. VIII	Certain observations on the international application
<input checked="" type="checkbox"/> Box No. I	Basis of the opinion																	
<input type="checkbox"/> Box No. II	Priority																	
<input type="checkbox"/> Box No. III	Non-establishment of opinion with regard to novelty, inventive step and industrial applicability																	
<input type="checkbox"/> Box No. IV	Lack of unity of invention																	
<input checked="" type="checkbox"/> Box No. V	Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement																	
<input type="checkbox"/> Box No. VI	Certain documents cited																	
<input type="checkbox"/> Box No. VII	Certain defects in the international application																	
<input type="checkbox"/> Box No. VIII	Certain observations on the international application																	
Date of submission of the demand 04.05.2005	Date of completion of this report 23.11.2005																	
Name and mailing address of the international preliminary examining authority:  European Patent Office D-80298 Munich Tel. +49 89 2399 - 0 Tx: 523656 epmu d Fax: +49 89 2399 - 4465	Authorized Officer Winger, R Telephone No. +49 89 2399-8129																	



**INTERNATIONAL PRELIMINARY REPORT
ON PATENTABILITY**

International application No.
PCT/EP2004/007374

Box No. I Basis of the report

1. With regard to the **language**, this report is based on the international application in the language in which it was filed, unless otherwise indicated under this item.
 - This report is based on translations from the original language into the following language, which is the language of a translation furnished for the purposes of:
 - international search (under Rules 12.3 and 23.1(b))
 - publication of the international application (under Rule 12.4)
 - international preliminary examination (under Rules 55.2 and/or 55.3)
2. With regard to the **elements*** of the international application, this report is based on (*replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report*):

) **Description, Pages**

1-9 as originally filed

Claims, Numbers

1-9 as originally filed

a sequence listing and/or any related table(s) - see Supplemental Box Relating to Sequence Listing

3. The amendments have resulted in the cancellation of:
 - the description, pages
 - the claims, Nos.
 - the drawings, sheets/figs
 - the sequence listing (*specify*):
 - any table(s) related to sequence listing (*specify*):
4. This report has been established as if (some of) the amendments annexed to this report and listed below had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).
 - the description, pages
 - the claims, Nos.
 - the drawings, sheets/figs
 - the sequence listing (*specify*):
 - any table(s) related to sequence listing (*specify*):

* If item 4 applies, some or all of these sheets may be marked "superseded."

**INTERNATIONAL PRELIMINARY REPORT
ON PATENTABILITY**

International application No.
PCT/EP2004/007374

Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes:	Claims	1-9
	No:	Claims	
Inventive step (IS)	Yes:	Claims	1-9 (see separate sheet)
	No:	Claims	
Industrial applicability (IA)	Yes:	Claims	1-9
	No:	Claims	

2. Citations and explanations (Rule 70.7):

) **see separate sheet**

**INTERNATIONAL PRELIMINARY
REPORT ON PATENTABILITY
(SEPARATE SHEET)**

International application No.

PCT/EP2004/007374

Re Section V

1. **Prior Art:** Reference is made to the following documents cited in the International Search Report

D1: US 2003/008020 A1
D2: US 2002/034557 A1
D3: DREWES SIEGFRIED E ET AL: "Recent findings on natural products with erectile-dysfunction activity." PHYTOCHEMISTRY. APR 2003, vol. 62, no. 7, April 2003 (2003-04), pages 1019-1025, XP004410106 ISSN: 0031-9422
D4: EP-A-0 304 603
D5: EP-A-0 418 806
D6: EP-A-0 692 250
D7: US 2002/013280 A1

- 1.1 Document D1 discloses methods for treating sexual dysfunction in males and females by administering an agent which remodels neuronal or vascular pathways. Examples are vasodilators, activators of guanylyl cyclase such as forskolin or antagonists of phosphodiesterases. Topical administration is also described. Document D2 discloses topical compositions comprising mixtures of plant extracts (especially Coleus forskohlii) for the treatment of female sexual disorders. Document D3 discloses forskolin as an intracavernosal vasoactive agent in the management of vasculogenic impotence. Combination of agents resulted in synergistic response.
- 1.2 Document D4 discloses the use of ximemic acid, topically administered, to treat sexual impotence.
- 1.3 Document D5 discloses topical compositions of Ammi extracts comprising particularly visnadine, which is more active if percutaneously administered and which increases volume and blood flow-rate.
- 1.4 Document D6 discloses topical compositions comprising esculoside for treating peripheral vasculopathies related to impaired peripheral microcirculation.

**INTERNATIONAL PRELIMINARY
REPORT ON PATENTABILITY
(SEPARATE SHEET)**

International application No.

PCT/EP2004/007374

1.5 Document D7 discloses icariin for treating sexual dysfunction and vasculogenic disease (enhancement of NO-cGMP pathway).

2. **Novelty and Inventive Step (Article 33(2) and (3) PCT):**

Claim 1 relates to a topical composition comprising a) esculoside or visnadine b) forskolin or plant extracts and c) esters of ximeninic acid, claim 9 relates to the use of said composition for treating sexual dysfunctions.

As none of the prior art documents disclose such a composition, the subject-matter of claims 1-9 seems to be novel.

In view of the data submitted by the applicant with respect to a synergistic effect of the gel according to example 1 of the application the subject-matter of the claims insofar as they relate to a compositions containing (at least) esculoside, coleus forskolii purified extract and ximeninic acid ethyl ester seems to be inventive.

With respect to the other compositions encompassed by claims 1-9 it is noted that they consist merely in the combination of known compounds for the same use or of known compounds with known properties which are employed for the same use, respectively (see documents D1-D7). Thus, the subject-matter of claims 1-9 insofar as they relate to these compositions does not seem to be inventive.

)